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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,049	12/01/2003	Erming Xia	P03373	2954
23702 7590 06/27/2007 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER CHORBAJI, MONZER R	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,049	Applicant(s) XIA ET AL.	
	Examiner MONZER R. CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final action is in response to the RCE/Amendment received on 06/06/2007

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As to newly amended claim 11, the specification as a whole does not provide a composition consisting of a buffer system, a chelating agent, one or more surfactants and one or more quarternized ammonium cationic polysaccharides. The same applies to the newly amended claim 12 where the specification does not teach such a combination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5-6 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al (U.S.P.N. 4,436,730).

Regarding claim 1, Ellis discloses an aqueous ophthalmic solution (col.1, lines 61-67 and col.5, lines 9-15) that includes quarternized ammonium cationic polysaccharides (col.10, lines 26-41 and examples VI-VII. JR-125; JR-400; JR-30M. See Applicant's specification [0019]) in an amount effective for solution preservation (example VI and col.2, lines 54-62). Ellis teaches the use of a buffer system (col.7, lines 55-57) and a chelating agent (col.7, lines 47-49). As to the amendment to the claim changing the transitional phrase comprising to consisting of, Ellis discloses the solution consists essentially of the polymer in a water solution. One of ordinary skill in the art would readily recognize that water is provided for dilution only and if so desired it would have been obvious to exclude the water in order to provide a more concentrate solution when cost is not a factor.

Regarding claims 3 and 6, Ellis employs variations of polyquaternium 10 (example IV).

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Regarding claim 5, Ellis discloses a method for producing a composition where cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62) As to the limitation, "consisting of", Ellis teaches that the use of a buffer system (col.7, lines 55-57) or a chelating agent (col.7, lines 47-49) is optional and is not basic and required part of the composition (col.7, lines 44-49) that if desired, it can be included in the composition. Note the specification in paragraph 0022 teaches that the use of buffers is optional and the use of sequestering agent (also known as chelating agent) is also optional as mentioned in paragraph 0027. One of ordinary skill in the art would recognize that in certain embodiments the composition would include an aqueous ophthalmic solution along with quarternized ammonium cationic polysaccharides as the only source of preservatives (as the instant amended claim recites) while in other embodiments additional additives such as buffers and chelating agents are added to the quarternized ammonium cationic polysaccharides.

Regarding claims 13-14, Ellis discloses a method of using a composition where cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62) where surfaces of contact lenses (i.e., medical items) are treated over a time interval so that microbial burden (col.2, lines 59-62 and col.7, lines 59-61) on contact lenses is eliminated.

6. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al (U.S.P.N. 5,401,327).

Regarding claim 10, Ellis discloses a solution for treatment of contact lenses (col.1, lines 6-8) where the solution includes quarternized ammonium cationic polysaccharides (col.4, lines 63-67 and example 7). Ellis teaches the use of a buffer system col.5, lines 12-15), a chelating agent (col.5, lines 46-48) and a tonicity agent (col.5, lines 10-11). Note that two components are required for this composition. They are polyethylene oxide and a cationic cellulosic polymer as mentioned in column 2, lines 16-39). In addition, Ellis recognizes the relationship between tonicity agents and the osmotic value of the solution (col.5, lines 18-21) and provides value ranges for its value as shown in Table 7 or Table 9. As to the amendment to the claim changing the transitional phrase comprising to consisting of, Ellis discloses the solution consists essentially of the polymer in a water solution. One of ordinary skill in the art would readily recognize that water is provided for dilution only and if so desired it would have been obvious to exclude the water in order to provide a more concentrate solution when cost is not a factor.

Regarding claim 11, Ellis discloses a solution for treatment of contact lenses (col.1, lines 6-8) where the solution includes quarternized ammonium cationic polysaccharides (col.4, lines 63-67 and example 7). Ellis teaches the use of a buffer system (col.5, lines 12-15), a chelating agent (col.5, lines 46-48) and a surfactant (col.5, line 37). Note that two components are required for this composition. They are polyethylene oxide and a cationic cellulosic polymer as mentioned in column 2, lines 16-39). In addition, Ellis recognizes the relationship between tonicity agents and the osmotic value of the solution (col.5, lines 18-21) and provides value ranges for its value

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as shown in Table 7 or Table 9. As to the amendment to the claim changing the transitional phrase comprising to consisting of, Ellis discloses the solution consists essentially of the polymer in a water solution. One of ordinary skill in the art would readily recognize that water is provided for dilution only and if so desired it would have been obvious to exclude the water in order to provide a more concentrate solution when cost is not a factor.

Regarding claim 12, Ellis discloses a solution for treatment of contact lenses (col.1, lines 6-8) where the solution includes quarternized ammonium cationic polysaccharides (col.4, lines 63-67 and example 7). Ellis teaches the use of a buffer system (col.5, lines 12-15), a chelating agent (col.5, lines 46-48) and a viscosity agent (col.5, line 61). Note that two components are required for this composition. They are polyethylene oxide and a cationic cellulosic polymer as mentioned in column 2, lines 16-39). In addition, Ellis recognizes the relationship between tonicity agents and the osmotic value of the solution (col.5, lines 18-21) and provides value ranges for its value as shown in Table 7 or Table 9. As to the amendment to the claim changing the transitional phrase comprising to consisting of, Ellis discloses the solution consists essentially of the polymer in a water solution. One of ordinary skill in the art would readily recognize that water is provided for dilution only and if so desired it would have been obvious to exclude the water in order to provide a more concentrate solution when cost is not a factor.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 3, 5-6 and 10-14 have been considered but are moot in view of the new ground(s) of rejection.

On bottom of page 4 to top of page 5 of the Remarks section, Applicant argues that Ellis employs an ionic polymer not cationic polymer. Applicant's specification, Paragraph 0019 recites examples of cationic polysaccharides that include, for example, JR 125 or JR 400. See example IV of Ellis where these compounds are provided as the preserving agent. Also, Ellis teaches that both anionic and cationic polymers are provided for alternating the polarity of the surface of the lens. For example, see the list for anionic and cationic polymers provided in columns 5-6. Also, see column 3, lines 40-41 and lines 60-62 with regards to alternating the polarity of lens surfaces.

On page 5 of the Remarks section, Applicant argues that Ellis teaching that additives can be added to the basic composition is improper to anticipate the instant claims. Ellis teaching that including various additives is a matter that depends on the choice of an artisan is not teaching theoretical possibilities. The reference is evaluated as a whole for every teaching that it recites. In evaluating the limitation," consisting of", Ellis (730) teaches that the use of a buffer system (col.7, lines 55-57) and a chelating agent (col.7, lines 47-49). Also, see the rejection above where it would have been obvious to one of ordinary skill in the art to exclude water from the solution.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

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9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRK


GLADYS J. CORCORAN
SUPERVISORY PATENT EXAMINER